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10/588,051	03/07/2007	Thomas Tallberg	U 016420-2	4058

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,051	TALLBERG, THOMAS	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10* is/are rejected.

7)☒ Claim(s) *8-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/1/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 2-10 are present for examination at this time.

Claim Objections

2. Claim 8 is objected to because of the following informalities: the work "zink" is misspelled. Appropriate correction is required.

3. Claim 9 is objected to because of the following informalities: a comma is missing after "vanadium (V)". Appropriate correction is required.

4. Claim 10 is objected to because of the following informalities: a comma is missing after "vanadium (V)". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2-7 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating psoriasis, does not reasonably provide enablement for preventing psoriasis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/use the invention commensurate in scope with these claims. The specification is only enabled for a method of treating psoriasis by using the composition recited but not for preventing psoriasis as claimed.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to the use of a composition comprising L-serine, L-isoleucine, chromium, tin, selenium, vanadium, and wolfram to treat or prevent psoriasis. Thus, the claims taken together with the specification imply that the composition is able to treat or prevent psoriasis.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The state of the art does not recognize psoriasis as curative as the cause is unknown (see Merck Manual sheets). The are common triggers and several modalities of treatment but no methods of prevention. The high degree of unpredictability in the treatment of skin diseases is well known in the art. The specification does not provide any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use as claimed of the instant composition.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the treatment of psoriasis.

However, the specification does not provide for any working examples against complete inhibition of psoriasis for preventative purpose.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the prevention of psoriasis wherein the cause of the condition is unknown and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

7. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claim is drawn to the incorporation and use of neurogenic lipids for psoriasis. There is inadequate written description for the term "neurogenic lipids". The specification does not provide an adequate description of what the components or the composition of the "neurogenic lipids" are. The specification does state a methodology

of obtaining the neurogenic lipids such as those from the brains of young pigs. The specification also states that the neurogenic lipids are purchased and canned by Neurofood Ltd.

However, this description is inadequate as there is no disclosure as to what are the specific components or lipids are used and as the "neurogenic lipids" are purchased from a commercial source with no disclosure of which specific product what purchased and utilized, it does not allow one of skill in the art to ascertain what the material is. Second if the commercial product is trademarked, the identification/description is indefinite. Where a trademark or trade name is used to identify or describe a particular material or product, the scope becomes uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2-10, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitations of zinc and folic acid following the phrase

are part of the claimed invention. It does not allow one of skill in the art to ascertain the metes and bounds of the invention.

10. Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 8-9 recites the broad recitation comprising, and the claim also recites "sole pharmaceutically active ingredients" which is the narrower statement of the range/limitation.

Additionally, the claims are drawn to comprising sole pharmaceutically active ingredients. The term "sole" is singular, thereby to one ingredient. This is unclear as the

claims are reciting "comprising" which is open language thereby inclusive of additional components and proceeds to list several components to the composition, not a single component. For purposes of examination, the overriding term is "comprising" and the composition is open to any number of components for the composition.

11. Claim 9 recites the limitation "chromium (Cr), tin (Sn), selenium (Se), vanadium (V) wolfram (W) and zinc (Zn) salts" in claim 8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bath (U.S. Pat. No. 6083293).

Bath teaches a composition comprising a calcium complex, humus extract, fucaceae extract, and yeast/molasses slurry solution. The composition contains chromium, selenium, tin, vanadium, tungsten (wolfram), zinc, isoleucine, serine, and folic acid. L-serine and L-isoleucine are isomers of serine and isoleucine and are inherently present in the composition.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

14. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Tallberg et al. (Studies on Mitochondrial Regulation of the Genome).

Tallberg et al. teaches compositions comprising amino acids and trace elements for bio-immunotherapy. specific components fed to a patient suffering from skin tumors (e.g. fibrotic histiocytoma, Merkel sarcoma, melanoma) comprised of isoleucine, serine, chromium, selenium, tin, vanadium, wolfram, manganese, folic acid, pig brain (neurogenic lipid), and multivitamins (see Page 134).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 2-7 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), as applied in claim 8 above, in view of Bodaness (U.S. Pat. No. 5563132), and further in view of Dong et al. (CN 1372926).

The teachings of Tallberg et al. are addressed above. Additionally, Tallberg teaches the use of these compositions comprising of isoleucine, serine, chromium, selenium, tin, vanadium, wolfram, manganese, folic acid, pig brain (neurogenic lipid),

and multivitamins for active immunotherapy to regress, heal, or transform the tumor into normal skin tissue. The trace elements are also presented in salt form.

Tallberg et al. does not expressly teach the use of these compositions for psoriasis or expressly recite the incorporation of zinc.

Bodaness teaches the use of a composition comprising metal ion complexes wherein several of the metal ions for the complexes are those in the instant invention (e.g. vanadium, chromium, manganese, tin, and tungsten/wolfram). The compositions were used for the treatment of skin cancers, premalignant lesions, psoriasis, and other skin conditions (Col.4, lines 39-48, Col.7, lines 33-40, Col.15, lines 26-36, Col. 16, line 3).

Dong et al. teaches the use of zinc (salt form-conjugated linoleate) for treating several conditions including skin cancer and psoriasis (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include zinc and utilize the compositions for psoriasis, as suggested by Bodaness and Dong, and produce the instant invention. It would have been obvious to combine two compositions (Tallberg composition and zinc by Dong) each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art. It is also obvious to try and utilize the composition for psoriasis as it is common in the art to utilize compositions that are useful for skin cancer/tumors for psoriasis as evidenced by both Bodaness and Dong.

One of ordinary skill in the art would have been motivated to do this because it is desirable to have improved and additive effects for treating a condition. It is also desirable to utilize a composition for other conditions when there is a suggestion in the art to use materials for skin cancer and psoriasis.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

17. Claims 2-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612